UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/815,580	03/31/2004	Larry Berger	293.100	2809

30040 7590 10/30/2007

MICHAEL A. SHIPPEY, PH. D.
LAW OFFICES OF KARLA SHIPPEY
4848 LAKEVIEW AVENUE, SUITE E
YORBA LINDA, CA 92886

EXAMINER	
OLSEN, KAJ K	

ART UNIT	PAPER NUMBER
1795	

MAIL DATE	DELIVERY MODE
10/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/815,580	BERGER ET AL.	
	Examiner	Art Unit	
	Kaj K. Olsen	1795	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-17 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-17 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 3-31-04.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: In the brief description of drawings, each figure number should be listed. For example, "Figures 3-6" should be --Figures 3, 4, 5, and 6--.

2. In the description of fig. 8 on p. 4, "clamber" should be --chamber--.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. In claim 1, the examiner believes the term "liquid junction salt bridges" should just be --liquid junctions-- as applicant only referred to the junctions in the specification as junctions. The examiner notes that the term "salt bridges" could be interpreted as requiring actual salt bridges (i.e. a bridge element filled with a salt) as opposed to a liquid junction providing the function that a salt bridge provides. For the purpose of examination, the examiner will presume that the claims are drawn to the broader use of liquid junctions as a whole, and not presume the claim requires an actual salt bridge.

6. The limitation drawn to the specified liquid junctions in claim 1 is confusing. In particular, applicant states that the bridges separate the chambers from each other and separate the chambers from the sample. This reads as if each bridge element is providing both functions, which is not the case. Rather one bridge separates the chambers from each other while the other bridge separates the sample from the chambers. This limitation should be clarified.

7. In claim 1, there is no antecedent basis for "two said half-cells". In particular, "half cells" should be --electrochemical half-cells--, and applicant only specified a plurality of electrochemical half-cells, not just two.

8. In claim 1, there is no antecedent basis for "said potential measurements".

9. Claim 3 is confusing because it specifies 3 electrochemical cells. First, "electrochemical cells" lacks antecedent basis. Second, it is unclear if "electrochemical cells" is meant to further define the number of electrochemical half-cells or just the number of electrochemical cells as a whole (i.e. can the ion selective electrode be construed as being an electrochemical cell of claim 3). Third, the claim is worded as if the device of claim 1 further comprises an additional three electrochemical cells. Hence, claim 3 would require the presence of *five* electrochemical cells (i.e. the two already defined by claim 1 and the three additional cells of claim 3), which the applicant doesn't teach. Claim 3 should be amended to state that the plurality of electrochemical half-cells of claim 1 is three to avoid this confusion.

10. In claims 4 and 5, there is no antecedent basis for "one said electrochemical cell".

11. In claim 6, there is no antecedent basis for "the diagnostic half-cell cell". Furthermore, it is entirely unclear what applicant is claiming here. In particular, applicant appears to be claiming a half-cell to monitor the diagnostic half-cell, but the diagnostic cell is the cell being

utilized for the monitoring of other cells. Where did applicant set forth an additional cell for monitoring the diagnostic cell?

12. In claims 8 and 10, there is no antecedent basis for "the exterior housing" or "said exterior housing".

13. In claim 11, there is no antecedent basis for "said shell". Furthermore, even if the examiner were to interpret "said shell" as being somehow related to the housing of claim 1, claim 11 would then appear to contradict claim 1 that required all the electrochemical cells to be under the housing.

14. In claim 12, there is no antecedent basis for "said half-cells".

15. Claims 13-17 provides for the use of the sensor of claim 1, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

16. Claims 13-17 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

18. Claims 1-15 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bryan (USP 4,822,456) in view of Itsygin (USP 6,322,680).

19. With respect to claim 1, Bryan discloses an electrochemical sensor comprising a plurality of chambers (14, 17) each filled with electrolyte, a plurality of electrodes (16, 18) each inserted into the chambers thereby forming a plurality of electrochemical half-cells, at least two liquid junctions (20, 22) separating the chambers from each other and from the sample being measured, an ion-specific detection means 30, a means for measuring and quantifying the electronic potential at the plurality of the half-cells (54 or 78), and a means for converting the potential measurements into a visual display 66. See fig. 1, 2, 4, and 5, col. 4, ll. 40-64, col. 5, l. 53 through col. 6, l. 12, and col. 7, ll. 48-53. Bryan does not explicitly disclose the use of a housing over all the earlier elements. However, it is conventional in the electrochemical sensor art to combine both the reference electrode (of which electrodes 16 and 18 of Bryan comprise) and indicator electrode into a single housing unit. This is demonstrated by the teaching of Itsygin, which combined all the sensor components into a single housing unit that provides greater ease of sensor operation and places the measuring and reference electrodes a fixed distance from each other. See fig. 1 and col. 3, ll. 39-46. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Itsygin for the sensor of Bryan so that all the electrode components are conveniently provided in one housing.

20. With respect to junctions 20 and 22 of Bryan being salt bridges, the examiner has interpreted applicant's use of this term as being drawn to not only physical salt bridges, but also

to conventional junctions in the art that provide the traditional function that salt bridges provide (see 112 rejection above). This is evidenced by the instant invention where the term "salt bridge" to describe elements 7 and 11 doesn't occur until the claims themselves. In the specification, they are merely described in the text as being "liquid junctions".

21. With respect to claim 2, cell formed by chamber 14 and electrode 16 of Bryan is physically isolated from the sample being measured by both junctions 20 and 22 and its potential (as with any reference electrode) should be ideally independent of concentration.

22. With respect to claim 3, the cells formed by the electrodes 16, 18, and 32 of Bryan would read on the defined three electrochemical cells. Moreover, solution ground provided by electrode 36 would also constitute another electrochemical cell.

23. With respect to claims 4 and 5, cell formed by electrode 18 of Bryan is functioning as a diagnostic cell and is indirect contact with the sample via junction 22. See fig. 1 and col. 5, l. 59 through col. 6, l. 2 of Bryan.

24. With respect to claim 6, it is entirely unclear what applicant is attempting to claim with this claim (see 112 rejection above). Regardless, the function of any unspecified electrochemical cell does not further define the structure of the cell.

25. With respect to claim 7, housing 14 of Bryan is entirely within housing 17 (see fig. 1).

26. With respect to claim 8, see col. 4, ll. 29-38 of Itsygin. Utilizing said metal housing as a solution ground constitutes the intended use of the apparatus and the intended use need not be given further due consideration in determining patentability.

27. With respect to claim 9, utilizing one of the electrochemical cells as a solution ground constitutes the intended use of the apparatus and the intended use need not be given further due

consideration in determining patentability. However, electrode 36 provides a solution ground. See Bryan, col. 5, ll. 38-42.

28. With respect to claim 10, see Itsygin, col. 8, ll. 5-10. Polystyrene is a non-conductive material.

29. With respect to claim 11, even though it appears to contradict claim 1 (see 112 rejection above), because Bryan already disclosed that none of the electrochemical half-cells need to be within a housing to provide appropriate sensing behavior, one possessing ordinary skill in the art would have been motivated to utilize at least one of the electrodes outside of the housing to yield the predictable result of having a still functioning electrochemical sensor.

30. With respect to claim 12, that is only the intended use of the apparatus and the intended use need not be given further due consideration in determining patentability. However, the potential Eb measured by Bryan appears to be entirely equivalent to the e2-e3 potential measured by the instant invention. Hence, Eb would also be a measure of a change in the chemical gradient as well.

31. With respect to claims 13 and 14, see col. 5, l. 53 through col. 6, l. 2.

32. With respect to claims 15 and 17, see col. 7, ll. 45-56.

33. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bryan and Itsygin as applied to claim 1 above, and further in view of Neukum (USP 5,139,641).

34. The references set forth all the limitations of the claim and Bryan further suggested setting degradation limits (i.e. thresholds) for the half-cells (col. 7, ll. 45-48), but did not explicitly recite replacement of the sensors when said degradation limits are reached. Neukum teaches that electrodes should be replaced when they have been found to be degraded. See col.

3, ll. 29-36. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Neukum and replace the half-cells of Bryan and Itsygin when they have been found to be degraded such that the sensor device can continue to be utilized without the concern of inaccurate measurements.

Conclusion

35. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Jäckle (USP 4,686,011) also discloses a sensor configuration largely analogous to the instant invention. See fig. 2 and 3.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kaj Olsen whose telephone number is (571) 272-1344. The examiner can normally be reached on Monday through Friday from 8:00 A.M. to 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen, can be reached on 571-272-1342. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AU 1795
October 25, 2007

KAJ K. OLSEN
PRIMARY EXAMINER